510(k) SUMMARY

Applicant name: Elettronica Valseriana srl
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Contact person: Sergio Ghersini
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Trade Name: MINNIE

Preparation Date: May 21st, 2014

Classification: Name: Electrosurgical, cutting & coagulation device & accessories
Product code: GEI
Regulation: 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description: MINNIE is a noninvasive radiofrequency device consisting of:

- Touch Screen User interface
- Programmable Microcontroller
- RF Power Module
- 4 Treatment Handpieces with following characteristics
  - Bipolar Handpiece Ø 36mm
  - Unipolar Handpieces Ø 36mm, 60mm and 80mm

MINNIE is a portable system used to deliver radiofrequency energy to the patient treatment site via a delivery handpiece.

Indications for Use: Noninvasive treatment of mild to moderate facial wrinkles and rhytides. This device has not been tested on darker skin subjects.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510(k) Number	Clearance Date	Name	Product code	Regulation	Class	Panel
Accent™	K070004	2007.04.23	Electrosurgical, cutting & coagulation device & accessories	GEI	21 CFR 878.4400	II	General & Plastic Surgery
Imagine TC Skin Treatment System	K083461	2009.07.24	Electrosurgical, cutting & coagulation device & accessories	GEI	21 CFR 878.4400	II	General & Plastic Surgery
Venus Freeze system	K100586	2010.11.29	Electrosurgical, cutting & coagulation device & accessories	GEI	21 CFR 878.4400	II	General & Plastic Surgery

An extended comparison is presented in Document Substantial equivalence discussion.

Performance Standards:
MINNIE complies with the following Recognized standards:

- IEC 60601-2-2:2009 – Medical Electrical Equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (with US/Canada deviations)
- IEC 60601-1-2:2007 – Medical Electrical Equipment Part 1 – General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests and the following voluntary standard
- IEC 60601-1:2005 – Medical Electrical Equipment Part 1 – General requirements for safety

In addition it complies with European Directive 93/42/EEC for Medical Devices (Annex IX – Rule 9).

Clinical Performance Study:
A clinical study has been carried out in order to assess the safety and effectiveness of MINNIE. To measure effectiveness, success criterion was defined as at least 2 points decrease in in the FWS score. Adverse events were monitored to evaluate safety.

The population included 52 subjects (36 females, 16 males). At the enrollment visit, their condition was evaluated using Fitzpatrick Wrinkles Scale (FWS) and they were randomly assigned to 3 groups:

Group A: control (only visit, no stimulation), 8 subjects
Group B: sham (electrical stimulation), 11 subjects
Group C: radiofrequency treatment, 33 subjects. (active treatment group)

Evaluations were performed by the investigator on live study subjects and documented with clinical photographs. To confirm the in-vivo scores, evaluations from a team of 3 physicians blinded to the randomization group were carried out on photographs. There were no differences in the scoring of the evaluators.

Subjects in Group A received no treatment, and subjects in Group B received electrical stimulation (sham treatment). All the subjects included in Group C received a cycle of 4 treatments 2 weeks apart. The treatments for Group C were applied using monopolar and bipolar electrodes delivering 550 kHz to 800 kHz energy up to a maximum 30 W radiofrequency energy and 30 W thermal energy for specified duration.

At 1 month after the end of the cycle, a new evaluation was carried out using the FWS scale. Data analysis showed a substantial improvement, as all the subjects treated met the above success criterion (at least 2 points decrease on the FWS).

The initial clinical protocol did not include a scheduled follow up visit for clinical evaluation at 3 and 6 months after last treatment. Upon FDA request clinical information with FWS scores and clinical photographs as well as investigators evaluation were submitted, the results are summarized below:

All subjects were followed up at 3 and 6 month time points. Outcomes for Group C at the 3 and 6 months follow-up visit are:

- all of the patient population treated demonstrated an improvement from baseline.
- at 3 months, in 42% of cases in the C group there was no change in the FWS score recorded at the completion of the treatment cycle.
- at 6 months, 44% of the subjects in the C group showed an improvement with respect to the FWS score recorded at 3 months, confirming the continuation of the treatment effect.

- 30% of the requested study subject photographs at 6 months were not provided to the Agency for review due to patient privacy privilege.

The only adverse events reported in this study were 4 cases of moderate skin erythema which resolved with the use of antihistamines and/or topical corticosteroids and skin emollients for a short period of time (maximum of 3 days).

No decrease in FWS was noticed in any subject in Group A (control) or Group B (sham) at the 3 or 6 month follow-up time points.

Rationale for substantial equivalence:

A comparison of Indicated Use Statement and technological characteristics to other predicates has been performed. The indications for use of the MINNIE device were found to be equivalent to the predicate devices and do not raise new questions of safety and effectiveness. Performance testing further demonstrated that the device can output the listed monopolar and bipolar energy, and therefore demonstrated that the technological characteristics can be considered substantially equivalent. As summarized above, clinical performance data was collected to demonstrate safety and effectiveness. These data show that subjects obtained an improvement in the FWS immediately following treatment, and maintenance of that improvement was obtained at 3 and 6 months. Therefore, the indications for use, technical characteristics and clinical study information provided demonstrates that MINNIE is substantially equivalent to the predicate devices.

Conclusion:
The MINNIE device shares the same indications for use, similar design and functional features, thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Elettronica Valseriana Srl
Mr. Sergio Ghersini
Regulatory Affairs Manager
Via South Carlo 45/47
24020 Casnigo (BG)
Italy

Re: K133405
Trade Name: Minnie
Regulatory Class: Class II
Product Code: GEI
Dated: December 6, 2013
Received: April 21, 2014

Dear Mr. Ghersini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.05.23 16:33:31 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133405

Device Name
MINNIE

Indications for Use *(Describe)*
Non-ablative treatment of mild to moderate facial wrinkles and rhytides.
This device has not been tested on darker skin subjects

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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